

UNITED STATES DISTRICT COURT FOR THE  
SOUTHERN DISTRICT COURT OF TEXAS  
HOUSTON DIVISION

UNITED STATES OF AMERICA and STATES §  
OF TEXAS, COLORADO, FLORIDA, §  
GEORGIA, ILLINOIS, LOUISIANA, §  
MARYLAND, NEW JERSEY, NORTH §  
CAROLINA, and OKLAHOMA; §  
COMMONWEALTH OF VIRGINIA; STATE §  
OF WASHINGTON; and THE DISTRICT OF §  
COLUMBIA, *ex rel.* §

CIVIL ACTION NO: 4:13-cv-1081  
(A Jury is Demanded)

MICHAEL VAUGHN, THEODORE §  
FREEMAN, WILLIAM MCKENNA, and §  
WESLEY STAFFORD, *Relators, Plaintiffs* §

vs. §

UNITED BIOLOGICS, LLC, d/b/a UNITED §  
ALLERGY SERVICES f/k/a UNITED §  
ALLERGY LABS; SMART ALLERGY LABS, §  
and ALLERGY PRACTICE CONSULTING §  
GROUP d/b/a ALLERTA CORP., *Defendants.* §

**DEFENDANT UNITED BIOLOGICS, LLC'S ANSWER AND DEFENSES**

Defendant United Biologics, LLC, d/b/a United Allergy Services, (hereinafter “UAS”) hereby answers the First Amended Complaint (Doc. 7) (the “Complaint”) filed by Relator-Plaintiffs Michael Vaughn, Theodore Freeman, William McKenna, and Wesley Stafford as follows. Except as otherwise admitted herein, UAS denies each of the allegations in the Complaint.

**I. INTRODUCTION**

1. Paragraph 1 of the Complaint contains no allegations directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint. Accordingly, said allegations stand denied.

2. UAS denies Relators' use of phrase "Defendants' illegal schemes" contained in Paragraph 2 of the Complaint, or that Relators allegedly learned of any such "schemes," or have any basis, unique, private, or otherwise, to allege the claims contained in the Complaint. UAS is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 2 of the Complaint. Accordingly, said allegations stand denied.

3. UAS admits it contracts with physicians to supply support services for physicians' provision of allergy testing and immunotherapy and the services are provided under a physician's care, supervision and/or orders. UAS denies all of the remaining allegations, including misleading references to "allergy centers," "Remote Allergy Centers," and any implication UAS or its technicians provide allergy testing or immunotherapy without supervision.

4. UAS denies the allegations in Paragraph 4 of the Complaint.

5. UAS denies any violations of the statutes and laws cited in the allegations in Paragraph 5 of the Complaint.

6. UAS denies the allegations in Paragraph 6 of the Complaint.

7. Responding to Paragraph 7 of the Complaint, UAS admits that Plaintiffs seek treble damages, civil penalties, and other relief. UAS denies all remaining allegations contained in Paragraph 7 of the Complaint.

8. UAS denies the allegations in Paragraph 8 of the Complaint.

9. Paragraph 9 of the Complaint contains no allegations directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint. Accordingly, said allegations stand denied.

## II. PARTIES

### A. Plaintiffs

10. The statements contained in Paragraph 10 of the Complaint call for a legal conclusion and contain no allegations as to UAS. However, to the extent any response is required, UAS denies the allegations contained in Paragraph 10 of the Complaint.

11. UAS denies Relators' use of phrase "illegal schemes" contained in Paragraph 11 of the Complaint, or any purported knowledge alleged by or attributed to Dr. Vaughn. Paragraph 11 of the Complaint contains no additional allegations directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint. Accordingly, said allegations stand denied.

12. UAS denies Relators' use of phrase "wrongful and illegal schemes" contained in Paragraph 12 of the Complaint, or any purported knowledge alleged by or attributed to Dr. Freeman. Paragraph 12 of the Complaint contains no additional allegations directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint. Accordingly, said allegations stand denied.

13. UAS denies Relators' use of phrase "wrongful and illegal schemes" contained in Paragraph 13 of the Complaint, or any purported knowledge alleged by or attributed to Dr. McKenna. Paragraph 13 of the Complaint contains no additional allegations directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 of the Complaint. Accordingly, said allegations stand denied.

14. UAS denies Relators' use of phrase "wrongful and illegal schemes" contained in Paragraph 14 of the Complaint, or any purported knowledge alleged by or attributed to Dr. Stafford. Paragraph 14 of the Complaint contains no additional allegations directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 of the Complaint. Accordingly, said allegations stand denied.

**B. Defendants**

15. UAS admits it is a Delaware limited liability company authorized to do business in Texas. UAS states that services are provided under a physician's care, supervision and/or orders. UAS denies the remaining allegations in Paragraph 15 of the Complaint.

16. Paragraph 16 of the Complaint contains no allegations directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 16 of the Complaint. Accordingly, said allegations stand denied.

17. Paragraph 17 of the Complaint contains no allegations directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 17 of the Complaint. Accordingly, said allegations stand denied.

**III. JURISDICTION**

18. UAS admits the allegations contained in Paragraph 18 of the Complaint.

19. UAS admits the allegations contained in Paragraph 19 of the Complaint.

**IV. VENUE**

20. UAS admits the allegations contained in Paragraph 20 of the Complaint.

## **VII. FACTUAL ALLEGATIONS**

### **A. Defendants' AKS Violations**

21. UAS denies the allegations contained in Paragraph 21 of the Complaint.

22. UAS admits it provides trained technicians and equipment pursuant to a valid, written agreement with physicians or practice groups. UAS denies the remaining allegations in Paragraph 22 of the Complaint.

23. Responding to the allegations in Paragraph 23 of the Complaint, UAS admits that physicians may direct UAS technicians to apply a skin test to patients to test for allergens, and denies any remaining allegations to the extent they apply to UAS. Any other allegations contained in Paragraph 23 of the Complaint are not directed against UAS, and thus no response is required from UAS. To the extent a response is required, UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 23 of the Complaint. Accordingly, said allegations stand denied.

24. UAS denies the allegations contained in the first and third sentences of Paragraph 24 on the Complaint. UAS is without knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second sentence of Paragraph 24 as they pertain to Smart Allergy. Accordingly, said allegations stand denied.

25. UAS denies the allegations in Paragraph 25 of the Complaint.

26. UAS states it provides protocols to physicians and some physicians may permit their patients to self-administer injections when the physician deems appropriate after the patient is properly trained. UAS denies the remaining allegations of Paragraph 26 of the Complaint as they pertain to UAS. UAS is without knowledge or information sufficient to form a belief as to

the truth of the allegations of Paragraph 26 as they pertain to Smart Allergy or Allerta. Accordingly, said allegations stand denied.

27. UAS denies the allegations contained in Paragraph 27 of the Complaint.

28. Responding to the allegations in Paragraph 28 of the Complaint, UAS admits that physicians or practice groups pay UAS fees for services UAS provides to the physicians or practice groups pursuant to a valid, written contract. UAS denies the remaining allegations contained in Paragraph 28 of the Complaint.

29. UAS denies the allegations in Paragraph 29 of the Complaint.

**B. Unnecessary Medical Services**

30. UAS denies the allegations in Paragraph 30 of the Complaint.

31. UAS denies the allegations in Paragraph 31 of the Complaint.

32. UAS denies the allegations in Paragraph 32 of the Complaint.

**C. Improper Billings for the Mixing and Dilutions of Allergens**

33. Responding to the allegations in Paragraph 33 of the Complaint, UAS admits that Medicare and Medicaid impose regulations, and such applicable regulations speak for themselves.

34. UAS denies the allegations as stated in Paragraph 34 of the Complaint.

35. Responding to the allegations in Paragraph 35 of the Complaint, UAS states that the Medicare guidelines speak for themselves. To the extent the allegations of Paragraph 35 of the Complaint do not fully and accurately reflect applicable Medicare guidelines, those allegations are denied.

36. Responding to the allegations in the first sentence of Paragraph 36 of the Complaint, UAS states that the referenced state rules and restrictions speak for themselves. To the

extent the allegations of Paragraph 36 of the Complaint do not fully and accurately reflect applicable state rules and restrictions, those allegations are denied. UAS denies the remaining allegations in Paragraph 36 of the Complaint.

**D. Improper Billing for SLIT**

37. UAS denies the allegations in Paragraph 37 of the Complaint.
38. UAS denies the allegations in Paragraph 38 of the Complaint.
39. UAS denies the allegations in Paragraph 39 of the Complaint.
40. UAS denies the allegations in Paragraph 40 of the Complaint.

**VIII. COUNTS AGAINST DEFENDANTS**

**Count 1: Violations of the FCA by All Defendants (pursuant to 31 U.S.C. 3729(a)(1) and 31 U.S.C. 3729(a)(2) [for violations before June 7, 2008] and pursuant to 31 U.S.C. 3729(a)(1)(A) and 31 U.S.C. 3729(a)(1)(B) [for violations on or after June 7, 2008]**

41. The statement contained in Paragraph 41 of the Complaint calls for a legal conclusion and contains no allegations as to UAS. However, to the extent any response is required, UAS denies the allegations contained in Paragraph 41 of the Complaint.
42. UAS denies the allegations as stated in Paragraph 42 of the Complaint.

**Count 2: Violations of the Anti-Kickback Statute, 42 U.S.C. 1320a-7b, Against All Defendants**

118. UAS denies the allegations as stated in Paragraph 118 of the Complaint.<sup>1</sup>
119. UAS denies the allegations as stated in Paragraph 119 of the Complaint.
120. UAS denies the allegations as stated in Paragraph 120 of the Complaint.
121. UAS denies the allegations as stated in Paragraph 121 of the Complaint.

**Count 3: Violations of the Texas Medicaid Fraud Prevention Law, TEX. HUM. RES. CODE §§36.001 et seq., Against Defendants**

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<sup>1</sup> UAS notes that the Complaint skipped paragraph nos. 43 – 117, and therefore no response is necessary.

122. UAS denies the allegations as stated in Paragraph 122 of the Complaint.

123. UAS denies the allegations as stated in Paragraph 123 of the Complaint.

**Count 4: Violations of the Colorado Medicaid False Claims Act, C.R.S. 25.5-4-305 et seq. Against UAL**

124. UAS denies the allegations as stated in Paragraph 124 of the Complaint.

125. UAS denies the allegations as stated in Paragraph 125 of the Complaint.

**Count 5: Violations of the Florida False Claims Act, Fla. Stat. §68.082(2)(a), (b), et seq., Against UAL**

126. UAS denies the allegations as stated in Paragraph 126 of the Complaint.

127. UAS denies the allegations as stated in Paragraph 127 of the Complaint.

**Count 6: Violations of the Georgia False Medicaid Claims Act, GA. CODE. ANN. §§49-4-168 et seq., Against UAL**

128. UAS denies the allegations as stated in Paragraph 128 of the Complaint.

129. UAS denies the allegations as stated in Paragraph 129 of the Complaint.

**Count 7: Violations of the Illinois False Claims Act, 740 ILL. COMP. STAT. §175/1, et seq., Against UAL**

130. UAS denies the allegations as stated in Paragraph 130 of the Complaint.

131. UAS denies the allegations as stated in Paragraph 131 of the Complaint.

**Count 8: Violations of the Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. ANN. §46:437.1 et seq., Against UAL**

132. UAS denies the allegations as stated in Paragraph 132 of the Complaint.

133. UAS denies the allegations as stated in Paragraph 133 of the Complaint.

**Count 9: Violations of the Maryland False Claims Act, MD. Health-General Code §2-601 et seq., Against UAL**

134. UAS denies the allegations as stated in Paragraph 134 of the Complaint.

135. UAS denies the allegations as stated in Paragraph 135 of the Complaint.

**Count 10: Violations of the New Jersey False Claims Act, N.J. STAT. ANN. §§2A:32C-1 et seq., Against UAL**

136. UAS denies the allegations as stated in Paragraph 136 of the Complaint.
137. UAS denies the allegations as stated in Paragraph 137 of the Complaint.

**Count 11: Violations of the North Carolina False Claims Act, N.C. GEN. STAT. §§1-6051 et seq., Against UAL**

138. UAS denies the allegations as stated in Paragraph 138 of the Complaint.
139. UAS denies the allegations as stated in Paragraph 139 of the Complaint.

**Count 12: Violations of the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63 §§5053.1 et seq., Against UAL**

140. UAS denies the allegations as stated in Paragraph 140 of the Complaint.
141. UAS denies the allegations as stated in Paragraph 141 of the Complaint.

**Count 13: Violations of the Virginia Fraud Against Taxpayers Act, VA. CODE ANN. §§8.01-216.1 et seq., Against UAL**

142. UAS denies the allegations as stated in Paragraph 142 of the Complaint.
143. UAS denies the allegations as stated in Paragraph 143 of the Complaint.

**Count 14: Violations of the Washington State Medicaid Fraud False Claims Act, RCW §§74.66 et seq., Against UAL**

144. UAS denies the allegations as stated in Paragraph 144 of the Complaint.
145. UAS denies the allegations as stated in Paragraph 145 of the Complaint.

**Count 15: Violations of the District of Columbia Procurement Reform Amendment Act, D.C. CODE ANN. §§2-308.13 et seq., Against UAL**

146. UAS denies the allegations as stated in Paragraph 146 of the Complaint.
147. UAS denies the allegations as stated in Paragraph 147 of the Complaint.

## **IX. PRAYERS FOR RELIEF**

148. UAS specifically denies that Plaintiffs are entitled to any of the relief sought in Paragraph 148 (including all subparagraphs) of the Complaint. Any additional allegations that

are contained in the Complaint, such as any allegations contained in headings, footnotes, attachments, or that are otherwise implied are hereby denied.

**X. JURY DEMAND**

280. UAS requests a jury trial.<sup>2</sup>

**ADDITIONAL DEFENSES**

**First Defense**

An award of damages and/or penalties (if any) greater than any damages actually sustained by the United States would be unconstitutional in violation of the Fifth, Sixth, and Eighth Amendments to the United States Constitution.

**Second Defense**

Relators' claims are barred because UAS has never submitted a false claim within the meaning of the FCA. Specifically, UAS acted properly and in accordance with AKS.

**Third Defense**

The United States has suffered no actual injury or damages because UAS did not submit, or cause to be submitted any false claims to the United States, any alleged claim was not material, and the United States has not been damaged or injured by UAS's conduct.

**Fourth Defense**

The Complaint fails to state a claim upon which relief may be granted.

**Fifth Defense**

Relators' claims are barred in whole or in part by the doctrine of unclean hands.

**Sixth Defense**

Relators' claims are barred in whole or in part by the doctrine of release.

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<sup>2</sup> UAS notes that the Complaint skipped paragraph nos. 148 – 279, and therefore no response is necessary.

### **Seventh Defense**

Relators' claims are barred in whole or in part by the doctrines of waiver or estoppel.

UAS further reserves the right to amend this Answer to include any additional defenses which may become known and/or available during this litigation.

WHEREFORE, having fully responded to the Complaint, UAS denies that it is liable to Relators in any way, either in law or equity. To the extent any paragraph, sentence, subparagraph, statement, or allegation in the Complaint is neither expressly admitted nor denied by the foregoing responsive answers and defenses, the same is hereby specifically denied. Further, any headings in the Complaint are assumed not to contain allegations, but to the extent they do, they are denied.

UAS respectfully requests that the Court enter an Order denying all of the claims against it as alleged in the Complaint, and that judgment be rendered in favor of UAS and against Relators, and that UAS be granted such other and further relief as the Court deems just, equitable, and proper, including, without limitation, its attorneys' fees.

Dated: September 12, 2016.

Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN  
LLP

/s/ *Casey Low*

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 12, 2016, the foregoing document was served on the following individuals via the Court's e-filing system.

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/s/ *Casey Low*  
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